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| APPLICATION NO.         | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 09/854,414              | 05/10/2001  | Gerald Horn          | HORN006CIP          | 7675             |
| 24573                   | 7590        | 12/15/2006           | EXAMINER            |                  |
| BELL, BOYD & LLOYD, LLC |             |                      | FAY, ZOHREH A       |                  |
| PO BOX 1135             |             |                      | ART UNIT            |                  |
| CHICAGO, IL 60690-1135  |             |                      | PAPER NUMBER        |                  |

1618

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/854,414 | <b>Applicant(s)</b><br>HORN, GERALD |  |
|                              | <b>Examiner</b><br>Zohreh A. Fay     | <b>Art Unit</b><br>1618             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10,11,13-15,18-40 and 43-73 is/are pending in the application.
- 4a) Of the above claim(s) 10,11,13-15,18-40 and 43-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 66-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Claims 10, 11, 13-15, 18-40 and 43-73 are pending in the instant application.

Claims 66-73 are presented for examination.

The response to the restriction requirement of March 27, 2006 has been received and entered. Applicant elected Group VI, claims 66-69 for examination purpose.

The newly added claims 70-73 will be examined with claims 66-69.

Applicant's arguments regarding the restriction requirement have been carefully considered, but are not deemed to be persuasive. Applicant in his remarks argues that claims 44-54 and 57-61 should be examined with the claims of GROUP VI. The arguments are not well taken since claims 44-54 and 57-61 are drawn to the combination of two active ingredients instead of one active ingredient of claims 66-69.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 66-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Galin (U.S. Patent 4,443,441). Galin teaches the use of the claimed alpha1 antagonist, phentolamine as a miotic agent in a pharmaceutical formulation. The above reference makes clear that the claimed composition is old and well known.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 66-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain alpha1 adrenergic antagonists, does not reasonably provide enablement for the broad phrase of "an alpha 1 antagonist". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are:

- 1) The nature of the invention:
- 2) The state of the prior art:
- 3) The relative skill of those in the art:
- 4) The predictability or unpredictability of the art:
- 5) The breadth of the claims:

The claims are very broad and encompass a composition using any alpha 1 antagonists being capable of disturbing endogenous compounds, which stimulates dilator muscles of a human eye.

- 6) The amount of direction or guidance provided:

Applicant's specification provides guidance for and it is only enabled for certain alpha 1 antagonists being capable of disturbing endogenous compounds which stimulate dilator muscles of human eyes. In *re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals

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and chemical compounds, which differ radically in their properties it must appear in applicant's specification either by the enumeration of a sufficient number of the members of the group or by other appropriate language, that the chemicals and chemical combinations included in the claims are capable of accomplishing the desired results." Applicant's specification does not set forth a representative number of examples of alpha 1 antagonists being capable of disturbing endogenous compounds, which stimulate the dilator muscle of human eye.

7) The presence or absence of working examples;

There are no examples in the specification directed to the use of alpha 1 antagonists being capable of disturbing endogenous compounds, which stimulate dilator muscles of human eye.

8) The quantity of experimentation necessary;

Since compound structure and activity for such pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all alpha 1 adrenergic antagonists being capable of disrupting endogenous compounds which stimulate dilator muscles of human eye.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Z.F

JOHN FAY  
PRIMARY EXAMINER  
GROUP 1800

*John Fay*